THE CLAIMS

What is claimed is:

1. A co-extruded dosage form comprising a core and a shell;

the core comprising an adverse agent, and

the shell comprising an active agent;

wherein the shell at least partially surrounds the core.

2. The co-extruded dosage form of claim 1, wherein the core further comprises a hydrophobic material.

3. The co-extruded dosage form of claim 2, wherein the shell surrounds a majority of the core.

4. The co-extruded dosage form of claim 3, wherein the shell further comprises a hydrophobic material.

5. The co-extruded dosage form of claim 1, wherein the active agent is an opioid agonist and the adverse agent is an opioid antagonist.

6. The co-extruded dosage form of claim 1, wherein the dosage form is an oral dosage form.

7. The co-extruded dosage form of claim 6, wherein the dosage form is a tablet or caplet.

8. The co-extruded dosage from of claim 6, wherein the dosage from is a capsule containing a plurality of particles.

9. The co-extruded dosage from of claim 8, wherein the particles range in size from about 0.1 mm to about 3.0 mm in all dimensions.

10. The co-extruded dosage form of claim 9, wherein the active agent is an opioid agonist and the adverse agent is an opioid antagonist.

11. The co-extruded dosage form of claim 10, wherein the dosage form provides controlled release of the opioid agonist following administration to a patient.

12. A co-extruded dosage form comprising:

a core comprising an adverse agent;

a sheath comprising a hydrophobic material which surrounds at least a portion of the core; and

a shell comprising an active agent which surrounds at least a portion of the sheath.

13. The co-extruded dosage form of claim 12, wherein the core further comprises a hydrophobic material.

14. The co-extruded dosage form of claim 12, wherein the sheath surrounds a majority of the core; and the shell surrounds a majority of the sheath.

15. The co-extruded dosage form of claim 12, wherein the shell further comprises a hydrophobic material.

16. The co-extruded dosage form of claim 12, wherein the hydrophobic material comprises a material selected from the group consisting of acrylic and methacrylic acid polymers and copolymers, alkylcelluloses, natural and synthetic waxes, water insoluble waxes, fatty alcohols, fatty acids, hydrogenated fats, fatty acid esters, fatty acid glycerides, hydrocarbons, hydrophobic and hydrophilic polymers having hydrocarbon backbones, and mixtures of any two or more of the foregoing.

17. The co-extruded dosage form of claim 16, wherein the hydrophobic material comprises an ammonio methacrylate copolymer.

18. The co-extruded dosage form of claim 12, wherein the dosage from is an oral dosage form.

19. The co-extruded dosage form of claim 18, wherein the oral dosage form is a tablet or caplet.

20. The co-extruded dosage of claim 18, wherein the oral dosage form is a capsule containing a plurality of particles.

21. The co-extruded dosage form of claim 12, wherein the active agent is an opioid agonist and the adverse agent is an opioid antagonist.

22. The co-extruded dosage form of claim 21, wherein the opioid agonist is selected from the group consisting of alfentanil, allylprodine, alphaprodine, anileridine, benzylmorphine, bezitramide, buprenorphine, butorphanol, clonitazene, codeine, desomorphine, dextromoramide, dezocine, diampromide, dihydrocodeine, dihydromorphine, dimenoxadol, dimepheptanol, dimethylthiambutene, dioxaphetyl butyrate, dipipanone, eptazocine, ethoheptazine, ethylmethylthiambutene, ethylmorphine, etonitazene, fentanyl, heroin, hydrocodone, hydromorphone, hydroxypethidine, isomethadone, ketobemidone, levallorphan, levorphanol, levophenacyl morphan, lofentanil, meperidine, meptazinol, metazocine, methadone, metophon, morphine, myrophine, nalbuphine, narceine, nicomorphine, norlevorphanol, normethadone, nalorphine, normorphine, norpipanone, opium, oxycodone, oxymorphone, papaveretum, pentazocine, phenadoxone, phenomorphan, phenazocine, phenoperidine, piminodine, piritramide, proheptazine, promedol, properidine, propiram, propoxyphene, sufentanil, tramadol, tilidine, pharmaceutically acceptable salts thereof, and mixtures of any two or more of the foregoing.

23. The co-extruded dosage form of claim 21, wherein the opioid agonist is selected from the group consisting of morphine, codeine, hydromorphone, hydrocodone, oxycodone, oxymorphone, dihydrocodeine, dihydromorphine, pharmaceutically acceptable salts thereof, and mixtures of any two or more of the foregoing.

24. The co-extruded dosage form of claim 21, wherein the opioid antagonist is selected from the group consisting of cyclazocine, naloxone, naltrexone, nalmefene, nalbuphine, nalorphine, cyclazacine, levallorphan, pharmaceutically acceptable salts thereof, and mixtures of any two or more of the foregoing.

25. The co-extruded dosage form of claim 21, wherein the opioid antagonist is selected from the group consisting of naloxone, naltrexone, nalmefene, pharmaceutically acceptable salts thereof, and mixtures of any two or more of the foregoing.

26. The co-extruded dosage form of claim 21, wherein the dosage form provides controlled release of the opioid agonist following administration to a patient.

27. The co-extruded dosage form of claim 21, wherein the dosage form releases about 0.5 mg or less of the opioid antagonist *in vivo* following administration to a patient.

28. The co-extruded dosage form of claim 21, wherein the dosage form releases about 0.05 mg or less of the opioid antagonist *in vivo* following administration to a patient.

29. A method for treating pain in a patient, comprising administering a co-extruded dosage form according to claim 12 to a patient, wherein the active agent is an opioid agonist and the adverse agent is an opioid antagonist.

30. A kit for treating pain in a patient, comprising:

a) a co-extruded dosage form according to claim 13, wherein the active agent is an opioid agonist and the adverse agent is an opioid antagonist; and

b) a printed set of instructions directing the use of the dosage form to treat pain in a patient.

31. A method of making a tamper-resistant dosage form comprising:

a) forming a multilayer extrudate by co-extruding:

a core comprising an adverse agent; and

a shell comprising an active agent which at least partially surrounds the core; and

b) rendering the multilayer extrudate to form at least one particle.

32. The method of claim 31, wherein the dosage form provides a controlled release of the active agent upon administration to a patient.

33. The method of claim 31, wherein the active agent is an opioid agonist and the adverse agent is an opioid antagonist.

34. The method of claim 33, wherein the opioid agonist is selected from the group consisting of alfentanil, allylprodine, alphaprodine, anileridine, benzylmorphine, bezitramide, buprenorphine, butorphanol, clonitazene, codeine, desomorphine, dextromoramide, dezocine, diampromide, dihydrocodeine, dihydromorphine, dimenoxadol, dimepheptanol, dimethylthiambutene, dioxaphetyl butyrate, dipipanone, eptazocine,

ethoheptazine, ethylmethylthiambutene, ethylmorphine, etonitazene, fentanyl, heroin, hydrocodone, hydromorphone, hydroxypethidine, isomethadone, ketobemidone, levallorphan, levorphanol, levophenacyl morphan, lofentanil, meperidine, meptazinol, metazocine, methadone, metophon, morphine, myrophine, nalbuphine, narceine, nicomorphine, norlevorphanol, normethadone, nalorphine, normorphine, norpipanone, opium, oxycodone, oxymorphone, papaveretum, pentazocine, phenadoxone, phenomorphan, phenazocine, phenoperidine, piminodine, piritramide, proheptazine, promedol, properidine, propiram, propoxyphene, sufentanil, tramadol, tilidine, pharmaceutically acceptable salts thereof, and mixtures of two or more of the foregoing.

35. The method of claim 33, wherein the opioid agonist is selected from the group consisting of morphine, codeine, hydromorphone, hydrocodone, oxycodone, oxymorphone, dihydrocodeine, dihydromorphine, pharmaceutically acceptable salts thereof, and mixtures of two or more of the foregoing.

36. The method of claim 33, wherein the opioid antagonist is selected from the group consisting of cyclazocine, naloxone, naltrexone, nalmefene, nalbuphine, nalorphine, cyclazacine, levallorphan, pharmaceutically acceptable salts thereof, and mixtures of two or more of the foregoing.

37. The method of claim 33, wherein the opioid antagonist is selected from the group consisting of nalmefene, naloxone, naltrexone, pharmaceutically acceptable salts thereof, and mixtures of two or more of the foregoing.

38. The method of claim 31, wherein the dosage form comprises a plurality of particles having a size of from about 0.1 mm to about 3 mm in all dimensions.

39. The method of claim 38, further comprising placing a plurality of particles into a capsule.

40. The method of claim 31, wherein the tamper-resistant dosage form is an oral dosage form.

41. The method of claim 31, wherein the core and the shell each comprise a hydrophobic material.

42. The method of claim 41, wherein the hydrophobic material is selected from the group consisting of acrylic and methacrylic acid polymers and copolymers, alkylcelluloses, natural and synthetic waxes, water insoluble waxes, fatty alcohols, fatty acids, hydrogenated fats, fatty acid esters, fatty acid glycerides, hydrocarbons, hydrophobic and hydrophilic polymers having hydrocarbon backbones, and mixtures of two or more of the foregoing.

43. The method of claim 42, wherein the hydrophobic material comprises an ammonio-methacrylate copolymer.

44. The method of claim 31, wherein the tamper-resistant dosage form provides a controlled release of the active agent *in vivo* for at least about 12 hours.

45. The method of claim 31, wherein the tamper-resistant dosage form provides a controlled release of the active agent *in vivo* for at least about 24 hours.

46. The method of claim 45, wherein the active agent is an opioid agonist, the adverse agent is an opioid antagonist; and the tamper-resistant dosage form releases about 0.5 mg or less of the opioid antagonist *in vivo* following administration.

47. The method of claim 46, wherein the tamper-resistant dosage form releases about 0.05 mg or less of the opioid antagonist *in vivo* following administration.

48. A method of making a tamper-resistant dosage form comprising:

a) forming a multilayer extrudate by co-extruding

a core comprising an adverse agent and a hydrophobic material;

a sheath comprising a hydrophobic material which at least partially surrounds the core; and

a shell comprising an active agent and a hydrophobic material which at least partially surrounds the sheath;

b) using a rolling punch to form one more particles from the multilayer extrudate; and

c) incorporating one or more particles into a dosage form.

49. The method of claim 48, wherein the dosage form provides a controlled release of the active agent upon administration to a patient.

50. The method of claim 48, wherein the active agent is an opioid agonist and the adverse agent is an opioid antagonist.

51. The method of claim 50, wherein the opioid agonist is selected from the group consisting of alfentanil, allylprodine, alphaprodine, anileridine, benzylmorphine, bezitramide, buprenorphine, butorphanol, clonitazene, codeine, desomorphine, dextromoramide, dezocine, diampromide, dihydrocodeine, dihydromorphine, dimenoxadol, dimepheptanol, dimethylthiambutene, dioxaphetyl butyrate, dipipanone, eptazocine, ethoheptazine, ethylmethylthiambutene, ethylmorphine, etonitazene, fentanyl, heroin, hydrocodone, hydromorphone, hydroxypethidine, isomethadone, ketobemidone, levallorphan, levorphanol, levophenacyl morphan, lofentanil, meperidine, meptazinol, metazocine, methadone, metophon, morphine, myrophine, nalbuphine, narceine, nicomorphine, norlevorphanol, normethadone, nalorphine, normorphine, norpipanone, opium, oxycodone, oxymorphone, papaveretum, pentazocine, phenadoxone, phenomorphan, phenazocine, phenoperidine, piminodine, piritramide, proheptazine, promedol, properidine, propiram, propoxyphene, sufentanil, tramadol, tilidine, pharmaceutically acceptable salts thereof, and mixtures of two or more of the foregoing.

52. The method of claim 50, wherein the opioid agonist is selected from the group consisting of morphine, codeine, hydromorphone, hydrocodone, oxycodone, oxymorphone, dihydrocodeine, dihydromorphine, pharmaceutically acceptable salts thereof, and mixtures of two or more of the foregoing.

53. The method of claim 50, wherein the opioid antagonist is selected from the group consisting of cyclazocine, naloxone, naltrexone, nalmefene, nalbuphine, nalorphine, cyclazacine, levallorphan, pharmaceutically acceptable salts thereof, and mixtures of two or more of the foregoing.

54. The method of claim 50, wherein the opioid antagonist is selected from the group consisting of nalmefene, naloxone, naltrexone, pharmaceutically acceptable salts thereof, and mixtures of two or more of the foregoing.

55. The method of claim 48, wherein the particles have a size of from about 0.1 mm to about 3 mm in all dimensions.

56. The method of claim 55, further comprising placing a plurality of particles into a capsule.

57. The method of claim 48, wherein the tamper-resistant dosage form is an oral dosage form.

58. The method of claim 48, wherein the hydrophobic material comprises at least one material selected from the group consisting of acrylic and methacrylic acid polymers and copolymers, alkylcelluloses, natural and synthetic waxes, water insoluble waxes, fatty alcohols, fatty acids, hydrogenated fats, fatty acid esters, fatty acid glycerides, hydrocarbons, hydrophobic and hydrophilic polymers having hydrocarbon backbones, and mixtures of two or more of the foregoing.

59. The method of claim 58, wherein the hydrophobic material comprises an ammonio-methacrylate copolymer.

60. The method of claim 48, wherein the tamper-resistant dosage form provides a controlled release of the active agent *in vivo* for at least about 12 hours.

61. The method of claim 48, wherein the tamper-resistant dosage form provides a controlled release of the active agent *in vivo* for at least about 24 hours.

62. The method of claim 61, wherein the active agent is an opioid agonist, the adverse agent is an opioid antagonist; and the tamper-resistant dosage form releases about 0.5 mg or less of the opioid antagonist *in vivo* following administration.

63. The method of claim 62, wherein the tamper-resistant dosage form releases about 0.05 mg or less of the opioid antagonist *in vivo* following administration.

64. A method of treating a condition, or a symptom thereof, in a patient comprising administering to the patient a tamper-resistant dosage form made according to the method of claim 48.

65. The method of claim 64, wherein the condition or symptom comprises pain.